

REMARKS

With entry of the instant amendment, claims 1-7, 11, and 14-27 have been cancelled; and new claims 38-41 have been added. Thus, claim 8, 9, 10, 12, 13, and 38-41 are currently pending in the application.

The amendments to the claims add no new matter. Claim 8 has been amended to recite detecting an increase in copy number of a gene encoding a Pellino 2 polypeptide comprising at least 95% amino acid identity to SEQ ID NO:4. Support can be found, *e.g.*, on page 7, lines 20-26.

Claims 8 and 9 have also been amended with regard to formatting. In addition, claim 9 has been amended to avoid redundancy.

Claim 10 has been amended to recite that the gene encoding the Pellino 2 polypeptide is amplified by a primer set of GATGCTGAAGTCGTCTCATTGG (SEQ ID NO:7) and CCAGTAGTTTAGCCTTTGTGGCTT (SEQ ID NO:8). Support can be found, *e.g.*, on page 55, lines 1-24.

The new claims are based on the specification and claims, *e.g.*, claim 10, as originally filed.

For convenience, the objections/rejections will be addressed in the order set forth in the Office Action dated January 12, 2005.

Specification

The specification has been amended to add the status of the provisional application from which the current application claims benefit; and to remove the hyperlinks. Applicants therefore request withdrawal of the objections.

Claim objections

Claims 8-13 were objected to as reciting limitations drawn to nonelected inventions. The amendments to the claims cancel the subject matter relating to the nonelected inventions. Applicants therefore request withdrawal of the objection.

Rejection under 35 U.S.C. § 112, first paragraph--written description

Claims 8-13 were rejected as allegedly lacking adequate written description support. The Examiner alleges that the specification does not describe a gene encoding a Pellino 2 polypeptide comprising at least 70% identity to SEQ ID NO:4, or degenerate variants of SEQ ID NO:3 that undergo an increase in copy number in cancer and can be used to detect cancer. To the extent that the rejection applies to the amended claims, Applicants respectfully traverse.

First, the Examiner contends that Applicants have not described structural features common to the members of the genus (page 6 of the January 12, 2005 Office Action). However, Applicants have taught that other Pellino 2 polypeptides, *e.g.*, mouse Pellino 2, are known in the art (*see, e.g.*, page 5, lines 19-23). Such polypeptide share a high degree of sequence identity, as evidenced by the sequence alignment provided in Appendix A. Thus, there is no reason to believe that one of skill would not understand what a Pellino 2 polypeptide that has 95% identity to the reference sequence is.

Second, The Examiner argues that Applicants have not specifically provided sequences of variants that have at least 95% identity to SEQ ID NO:4 that are overexpressed in cancer, and concludes that the claims therefore are not adequately described. However, the Examiner's conclusion is not properly based on the written description standards articulated by the Federal Circuit. To satisfy the written description requirement, an application must describe the claimed invention in sufficient detail that one skill in the art can reasonably conclude that the inventor had possession of the claimed invention (MPEP § 2163(I), citing *Moba, N.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19USPQ2d, 1111, 1116, emphasis added). Applicants currently claimed invention is the discovery that the *Pellino 2* locus is increased in copy number in epithelial cancers. The claims recite detection of a gene encoding a Pellino 2 polypeptide that has at least 95% to a reference sequence, which is intended to cover potential human allelic variants of SEQ ID NO:4, known or unknown. The Examiner provides no reasoning or evidence that the sequences of such alleles must be explicitly provided in order for

one of skill to understand that applicants had possession of the invention, *i.e.*, that the discovery that *Pellino 2* is increased in copy number in cancer.

"The examiner has the initial burden of presenting by a preponderance of evidence why a person skill in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims" (MPEP 2163.04, emphasis added). The Examiner has failed to meet this burden. In particular, the Examiner provides no evidence that naturally occurring allelic variants at the *Pellino 2* locus would not also undergo an increase in copy number in cancer. The Examiner provides no reasoning that one of skill would require that the sequences of allelic variants to be explicitly provided in order to recognize that applicants invented what is claimed: detection of epithelial cancer cells by detecting an increase in copy number of the *Pellino 2* locus. In summary, the Examiner fails to provide evidence that indicates that the ordinary artisan could not predict the operability in the invention of any species other than the one that is specifically disclosed, *i.e.*, in this case SEQ ID NO:4 (MPEP § 2163.(II)(A)(3)(ii)). Accordingly, the claims are adequately described by providing the specific sequence of only SEQ ID NO:4.

Third, the Examiner also alleges that the claimed invention lacks adequate written description because applicants have failed to describe degenerate variants of SEQ ID NO:3. Applicants traverse for the reason described above relating to allelic variants of the *Pellino 2* polypeptide sequence. Furthermore, the MPEP explicitly states that description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces, (MPEP § 2163.(II)(A)(3)(ii)). This passage provides an example from the molecular biology arts where, if an applicant discloses an amino acid sequence, it is unnecessary to provide an explicit disclosure of nucleic acid sequence that encode the amino acid sequence, citing to *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993). Accordingly, Applicants are not required to elaborate degenerate variants of SEQ ID NO:3 that encode SEQ ID NO:4 to provide adequate written descriptive support.

In view of the foregoing, the written description rejection is improper and should be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph--enablement

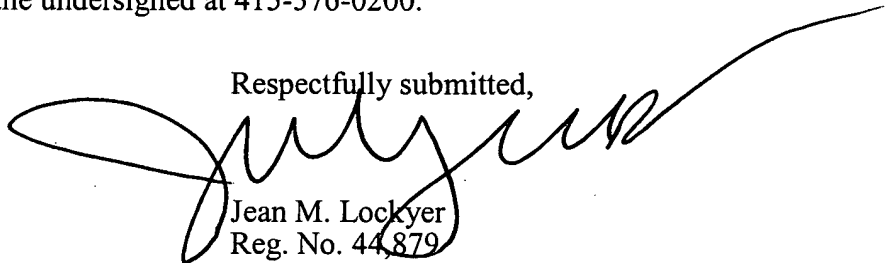
Claims 8-10 and 13 were also rejected as allegedly not enabled for detecting an increase in copy number of a gene encoding Pellino 2 in any type of cancer. Applicants believe that the amendment to claim 8 to recite that the cancer cells that are detected are epithelial cancer cells obviates this rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

A large, stylized handwritten signature in black ink, appearing to read 'JML', is written over the typed name and registration number.

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